IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' NOTICE OF ADOPTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE GENERAL OPINION TESTIMONY OF DR. E. STANTON SHOEMAKER, M.D.

In Wave 3 of this litigation, Plaintiffs adopt the *Daubert* motion they filed in relation to the general-causation opinions of E. Stanton Shoemaker, M.D., in Wave 1, Dkt. 2803. *See* Pls.' Notice of Adoption (Dkt. 2803). The Court has ruled on that Wave 1 motion. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493457 (S.D.W. Va. Aug. 25, 2016). Defendants Ethicon, Inc., Johnson & Johnson and, where applicable, Ethicon LLC (collectively, "Ethicon") respectfully request that this Court again deny Plaintiffs' motion for the reasons expressed below, and in accordance with this Court's August 25, 2016 Memorandum Opinion and Order.

ARGUMENT AND AUTHORITIES

I. Dr. Shoemaker Is Qualified to Provide Opinions Concerning the Biocompatibility Properties of Pelvic Mesh, and His Opinions on This Topic Are Reliable.

Plaintiffs assert the identical arguments regarding Dr. Shoemaker's opinions on the biocompatibility properties of pelvic mesh that they asserted in Wave 1. This Court has determined that Dr. Shoemaker is qualified to provide opinions "on mesh's reaction to and effect

on the human body," and that his opinions on this topic are reliable. *In re: Ethicon, Inc.*, 2016 WL 4493457, at *3. Ethicon respectfully requests that this Court rule in the same manner in the Wave 3 cases and again deny Plaintiffs' motion with respect to Dr. Shoemaker's opinions concerning the biocompatibility properties of pelvic mesh.

II. Dr. Shoemaker Is Entitled to Testify About the Risks of Implanting Mesh and Whether They Appeared in the IFU, and the Common Knowledge of Physicians Regarding Risks.

Dr. Shoemaker's proposed testimony is consistent with this Court's orders. The Court has determined that Dr. Shoemaker is qualified to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc.*, 2016 WL 4493457, at *3. Further, although the Court has excluded Dr. Shoemaker's testimony regarding "what 'all physicians' know or should know or what 'all physicians' rely on in making informed decisions," *id*. at *3, the Court has expressed no opinion regarding "whether certain risks were common knowledge," and therefore has not precluded this expert testimony. *See, e.g.*, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016) ("The plaintiffs' Motion focuses on whether Dr. Woods is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Woods may testify about whether certain risks were common knowledge."); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 n.2 (S.D.W. Va. Aug. 31, 2016) (same); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536875, at *4 n.2 (S.D.W. Va. Aug. 30, 2016) (same); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536872, at *3 n.2 (S.D.W. Va. Aug. 30,

2016) (same); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493666, at *4 n.2 (S.D.W. Va. Aug. 25, 2016) (same); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig*., MDL No. 2327, 2016 WL 4493681, at *3 n.2 (S.D.W. Va. Aug. 25, 2016) (same).

Dr. Shoemaker is qualified to testify regarding risks that are within the common knowledge of surgeons who perform pelvic surgeries. As detailed in Ethicon's Wave 1 Opposition, Dr. Shoemaker has extensive clinical experience with native-tissue surgical procedures, surgical procedures involving mesh, and mesh repairs. Defs.' Opp'n (Dkt. 2239) at 2-3. Because of his specialized knowledge and experience, Dr. Shoemaker often is asked to instruct other OB-GYNs in these techniques. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 2. He has served as a speaker and preceptor for surgeons at Ethicon-sponsored training sessions since the early 2000s. *Id.*; Ex. B to Pls.' Mot. (Dkt. 2104-2), Shoemaker Curriculum Vitae; Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 121:22-122:13. In those training sessions, he has demonstrated the proper way to implant Ethicon's TVT and POP devices, and also discussed information contained in the IFUs. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 2. In addition, Dr. Shoemaker relies on his review of complications reported in the medical literature, statements of leading medical societies, discussions with other surgeons, and general knowledge as a pelvic-floor surgeon in reaching his opinions. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 1-7, 20-27, 32-36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 1-8, 13, 17-25, 30-32; Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 136:9-16, 137:19-138:5, 156:10-157:1.

Because Dr. Shoemaker has the requisite foundation, he may offer his opinion that exposure/extrusion/erosion, chronic pain, and dyspareunia are generalized risks of mesh surgery

and such risks are within the common knowledge of surgeons who perform pelvic surgeries, including mesh implantations. Ex. C to Pls.' Mot. (Dkt. 2104-3), Shoemaker POP Device Report at 20-27, 32-36; Ex. D to Pls.' Mot. (Dkt. 2104-4), Shoemaker TVT Report at 13, 17-25, 30-32; Ex. E to Pls.' Mot. (Dkt. 2104-5), Shoemaker 4/5/16 Dep. Tr. 156:10-157:1.[1]

Thus, Ethicon respectfully requests that this Court deny Plaintiffs' motion to the extent it seeks to exclude Dr. Shoemaker's testimony regarding the common knowledge of physicians regarding risks associated with pelvic floor surgery, and risks of implanting mesh and whether they were included in the IFU.

III. Dr. Shoemaker Will Not Use Impermissible Legal Terms of Art in Expressing His Disclosed Opinions at Trial.

This Court has held that "an expert may not offer expert testimony using 'legal terms of art,' such as 'defective,' 'unreasonably dangerous,' or 'proximate cause.'" *In re: Ethicon, Inc.*, 2016 WL 4493457, at *5. Ethicon does not agree that all of the statements listed in Plaintiffs' Wave 1 motion contain legal terms of art, rather than permissible medical opinions. *See* Pls.' Mem. (Dkt. 2105) at 8-9. In the Wave 3 cases, however, Dr. Shoemaker will not express his disclosed opinions using impermissible legal terms of art at trial. Accordingly, this Court should deny the argument as moot.

[1] Moreover, this testimony will be helpful to juries assessing warning adequacy because a manufacturer has no duty to warn of those risks commonly known to the surgeons who use the device. As stated generally in the Restatement (Third) of Torts: Products Liability §2 cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§ 388(b), 402A cmt. j. In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added).

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' Motion to Exclude the General Opinion Testimony of E. Stanton Shoemaker, M.D. be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 11, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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